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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,680	07/01/2004	Wei Wang	MSB-7293	3098

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EXAMINER

HA, JULIE

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/500,680

Applicant(s)

WANG ET AL.

Examiner

Julie Ha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Peptide hormone superfamily: PACAP, PACAP-like peptide, VIP, glucagons, glucagons-like peptides, secretin, helodermin, exendin-4.

Peptide: adrenocorticotrophic hormone, angiotensins, rennin substrate tetradecapeptide, natriuretic peptides, gastrointestinal peptides, luteinizing hormone releasing hormone, melanocyte stimulating hormone, neurotensin, and parathyroid hormone.

Salt of transition metal: zinc, copper, iron, manganese, nickel, and cobalt.

Organic solvent: DMSO, 1-methyl-2-pyrrolidinone, propanol, propylene glycol, glycerol acetate, monothioglycerol, acetic acid, diethanolamine, benzyl alcohol, ethyl lactate, glycerol formal, N-methylpyrrolidone, polyethyleneglycol 400, and isopropyl myristate.

Dried mixture: an acid and a peptide (claim 17)

Inorganic acid: HCl and H₃PO₄

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

All disclosed variables must be elected to a single disclosed species. For example, one peptide from disclosed peptide hormone superfamily (from claims 2, 39, and 55), a single disclosed species from claims 5, 41, and 57, a single disclosed species of transition metal salt (from claims 6, 7, 24, 32, 42, 43, 52, and 58), a single disclosed species of organic solvent (from claims 8-10, 12-14, 36-38, and 61-63), a single disclosed species of inorganic acid (from claims 20, 29, and 46) are to be elected to form a single invention.

2. The claims are deemed to correspond to the species listed above in the following manner:

Claims 2, 5, 6, 8-10, 12-14, 17, 20-21, 24, 29, 32, 36-39, 41, 42, 46, 52, 55, 57, 58, 61, 62, and 63.

The following claim(s) are generic: 1, 11, 19, 23, 25, 28, 31, 35, 44, 45, 51, 54, and 60.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: The peptide hormone superfamily have different functions. For example, PACAP is important in the control of endocrine and homeostatic processes, such as secretion of pituitary and gut hormones and food intake, while glucagons play an important role in regulation of blood glucose concentration, ketone metabolism, and several other biochemical and physiological processes. The peptides such as adrenocorticotrophic hormone, angiotensins, rennin substrate tetradecapeptide, natriuretic peptides, gastrointestinal peptides, luteinizing hormone releasing hormone, melanocyte stimulation hormone, neurotensin and parathyroid hormone are different due to their different functions. For example, melanocyte-stimulating hormones are peptides with the ability to stimulate pigmented cells melanocytes in mammals, while luteinizing hormone releasing hormone stimulates the synthesis and secretion of both pituitary gonadotropins LH and FSH. The salt of a transition metal is different one from the other because these metals play different roles in biochemical and physiological processes. For example, iron's chief functions are in the transport of oxygen to tissue and in cellular oxidation mechanisms, while zinc plays a key role in protein synthesis and in cell division. Organic solvents are patentably independent and distinct due to their chemical structures. For example, benzyl alcohol has a chemical formula $C_6H_5-CH_2-OH$ while DMSO has a chemical formula $(CH_3)_2-SO$. Furthermore, benzyl alcohol is used as a local anesthetic and to reduce pain, while DMSO is used to protect tissue during cryopreservation. An acid and a peptide patentably independent and distinct due to their structures. Peptides are made up of amino acids, while acids are those chemical compounds which yield hydrogen ions or protons when dissolved in water, whose hydrogen can be replaced by metal or basic radicals, or which react with bases to form salts and water. Inorganic acids such as HCl and H_3PO_4 are patentably independent and distinct due to their acidity. HCl is a strong acid, while H_3PO_4 is a weak acid. Therefore, search for each disclosed species will be burdensome.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their

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recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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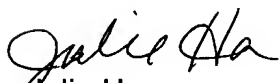
Conclusions


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Julie Ha
Patent Examiner


ANISH GUPTA
PRIMARY EXAMINER